

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Determining the effects of vitamin B12 on clinical outcome and complications of hospitalized covid-19 patients.

Protocol summary

Study aim

Determining the effects of vitamin B12 on clinical outcome and complications of hospitalized covid-19 patients.

Design

double blind randomized clinical trial. with control group, phase 3, 40 patients. block randomization

Settings and conduct

This study will be performed at Baharloo Hospital and patients will be given an oral vial of vitamin B-12. Also, the caregivers will be blind to the study.

Participants/Inclusion and exclusion criteria

inclusion criteria: consent age 18-75 years covid-19 patients hospitalized patients exclusion criteria: consent not given not within the 18-75 years old range needing ventilator acute/chronic kidney insufficiency liver insufficiency taking vitamin B12 in the past 3 months.

Intervention groups

in the first 24 hours of admission the level of vitamin B-12 will be checked and after that the oral vial of vitamin B-12 will be ordered for 7 days for covid-19 patients. control group will receive placebo with same volume.

Main outcome variables

Shortness of breath, ferritin, esr, crp, wbc, need for mechanical ventilation, mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210515051304N1**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

zahra erfani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3457 5525

Email address

zahraerfani1998@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-04, 1400/07/12

Expected recruitment end date

2021-12-03, 1400/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effects of vitamin B12 on clinical outcome and complications of hospitalized covid-19 patients.

Public title

Effect of vitamin B12 on hospitalized covid-19 patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

consent age 18-75 years covid-19 patients hospitalized

Exclusion criteria:

nodding ventilator acute/chronic renal insufficiency liver

insufficiency taking vitamin b12 in the past 3 months

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization in order to balance the randomization and blindness, four block are randomized during the study. in each block, there are two groups and and as the group is completed, the first block will be opened and four patients will be assign according to the first block. then enter the second block until the sufficient sample.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and caregivers will not know whether the medication is a placebo or the drug.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Qods Ave, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

12299

Approval date

2021-09-22, 1400/06/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.729

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07. 1

ICD-10 code description

COVID19, virus identified

Primary outcomes

1

Description

vitamin B12 blood level

Timepoint

before study, first 24 hours, day 7

Method of measurement

Blood sampling

2

Description

mortality

Timepoint

at the end of hospitalization

Method of measurement

observation

3

Description

need for mechanical ventilation

Timepoint

at the end of hospitalization

Method of measurement

file

4

Description

spo2

Timepoint

daily

Method of measurement

pulse oximeter

5

Description

vit-d blood level

Timepoint

day 1

Method of measurement

lab test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: B-12 vitamin 1000mg/daily, 7 days, oral

Category

Treatment - Drugs

2

Description

Control group: Vitamin B-12 placebo with the same volume, frequency, number of days and the same manufacturer

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo hospital

Full name of responsible person

dr. Neda Faraji

Street address

Baharloo Hospital, Behdari St., Railway Square, Tehran.

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baharloo@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

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Vesal shirazi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Neda Faraji

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

including criteria: Personal consent, Age between 18-75 years, Covid-19 positive and hospitalization.

When the data will become available and for how long

the start of access period is six months after results

To whom data/document is available

Dr. Neda Faraji Dr. Samaneh Akbarpour Dr. Nafiseh Sadat Alizadeh

Under which criteria data/document could be used

Necessary conditions will be reviewed by the Research committee after the petition.

From where data/document is obtainable

Refer to the Development and Research Center of Baharloo Hospital Research Unit.

What processes are involved for a request to access data/document

The letter is written to the Development Center and discussed to the Research Committee, which is given the necessary access after approval.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Neda Faraji

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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